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US-A- 3 867 728
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US-A- 4 344 193
US-A- 4 502 161

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Description

This invention relates to a soft tissue implant and more particularly to a meniscus cartilage replacement for a patient.

Wall U.S. Patent No. 4 502 161 discloses a meniscus cartilage replacement for a patient which consists of a woven fiber sheet coated with a resilient material with a lateral extension of the sheet extending outside the joint for anchoring to the side of the tibia with a screw. However, the wall replacement is thin and flat (two dimensional) and hence is non-anatomical in shape.

The following several patents are several of the references in the aforementioned Wall patent.

Kenny U.S. Patent No. 4 344 193 discloses a meniscus cartilage replacement of three dimensional shape. However, the Kenny replacement consists simply of a non-reinforced molded silicone rubber member. Although other possible ways are mentioned briefly in passing, the Kenny drawings show sutures and increased thickness ends as ways to hold the replacement in place in the joint, the increased thickness ends being discussed in detail.

Stubstad U.S. Patent No. 3 879 767 discloses an artificial implant but formed as a spinal disc replacement.

Homsy U.S. Patent Nos. 3 971 670 and 4 127 902 merely disclose artificial tension members which may be led through holes in bone and stapled for use as replacement tendons and ligaments. No cartilage replacement is shown.

In so far as the applicants are aware a fully satisfactory meniscus cartilage replacement has not been achieved in the prior art.

Accordingly, it is desired to provide a soft tissue implant in the form of a meniscus cartilage replacement for a patient, which combines an anatomical shape with woven and felted fiber interior reinforcement for strength and durability, in which coated top and bottom surfaces are capable of sliding with respect to adjacent tissues of the patient in a manner to simulate a natural meniscus cartilage, in which a convex, exterior edge is capable of receiving natural fibrous tissue ingrowth of the patient to, in time, naturally anchor the implant in the joint of the patient and in which, optionally, the implant can be positively anchored to adjacent bone while awaiting such natural fibrous tissue ingrowth.

According to the invention there is provided by providing a soft tissue replacement implant, such as a meniscus cartilage replacement, for a patient, which comprises appropriately shaped top and bottom layers sandwiching therebetween at least one intermediate felted layer, and a resilient bonding material coating the layers and holding same in a laminated condition. The intermediate layer(s) is cut narrower than the top and bottom layers and the layers have a common side edge. The top layer being contoured, to provide a wedge shaped cross section and a contoured three dimensional shape. A fabric member is bonded to the thickened edge of the resulting laminant and is porous to invite ingrowth of patient tissue to anchor the implant eventually in place. In addition, a method of making the implant involves coating of layers with a resilient bonding material, applying the layers one atop the next, and curing the resilient bonding material after each successive layer is applied.

Figure 1 is a pictorial view taken from the top and convex, exterior perimeter edge of a meniscus cartilage implant embodying the invention;

Figure 2 is an enlarged cross sectional view substantially taken on the line II-II of Figure 1;

Figure 3 is an exploded view of woven and felted components of the Figure 1 implant;

Figure 4A is a top view of a fragment of woven fabric superimposed by the outline of one of the Figure 3 components;

Figure 4B is an edge view of the Figure 4A sheet;

Figure 5A is a top view of a sheet of felted material superimposed by the outline of a corresponding Figure 3 component;

Figure 5B is an edge view of the Figure 5A felted sheet;

Figure 6 is a fragment of the Figure 2 cross sectional view but in an unfinished state;

Figure 7 shows in dotted lines a top view of the top woven layer component of the Figure 1 implant in a flat state, such component as shown in solid line being distorted into a three dimensional bowl segment shape;

Figure 8 is a top view of a tube of the Figure 1 implant;

Figure 9 is a fragmentary pictorial view of an end portion of the Figure 8 tube prior to trimming;

Figure 10 is a top view of an optional elongate tape of the Figure 1 implant;

Figure 11 is a schematic pictorial view showing a Figure 1 implant installed as a replacement for the natural medial meniscus cartilage in the knee joint of a patient.

Figure 1 shows a soft tissue implant 10 embodying the invention.

Although the present invention in its broader aspects is applicable to implants in other portions of the body of a human (or other mammal) patient, for convenience of illustration of a preferred embodiment, the particular implant 10 here shown is adapted for replacement of a meniscus cartilage in a human knee. The present invention is readily applicable to both the lateral and medial meniscus cartilages, but for convenient illustration, the embodiment shown is a replacement for the medial meniscus cartilage.

Thus in Figure 11, an implant 10 embodying the invention is shown installed atop the tibia 11 and be-

low the corresponding condyle of the femur 14 of a patient.

The medial meniscus cartilage implant 10 is anatomically shaped, namely three dimensionally shaped like the natural medial meniscus cartilage of the patient.

More particularly then, the implant 10 is a generally C-shaped (or kidney bean shaped) implant as seen in Figure 1 and is of wedge shaped central cross section, as shown in Figure 2.

The implant 10 comprises a body 20 having spaced apart ends. The body 20 has a perimeter edge 22, 23 comprising a concave perimeter edge 22 and a convex perimeter edge 23 (Figures 1 and 6). The convex perimeter edge 23 defines the ends 21 of the generally C-shaped body 20. The concave and convex perimeter edges are oppositely facing and spaced across the width of the generally C-shaped body 20. The body 20 has a flat bottom face 24 (Figure 6) and a sloped, preferably slightly concavely curved top surface 25. The central portion of the convex perimeter edge 23 is much thicker than the concave perimeter edge 22. For example, the central portion of the convex perimeter edge 23 may be about one-quarter inch high, whereas the concave perimeter edge is preferably a feather edge. The convex perimeter edge 23, at least in the central portion thereof, upstands substantially perpendicular from the bottom surface 24 of the body 20. The convex perimeter edge 23 tapers from the thick central portion 26 thereof toward the ends 21 of the body 20 (as can be generally seen in Figure 11), so that the convex perimeter edge 23 tapers substantially to a feather edge in the central portion 26 of the ends 21.

The body 20 (Figure 6) is a multi-layer laminate. In the preferred embodiment shown, such laminate comprises a woven cloth bottom layer 30 (Figures 3 and 4), and in successively stacked relation thereatop, at least a first felt intermediate layer 31, preferably a second felt intermediate layer 32 and a top cloth layer 33. More than two felted layers normally will not be needed. A resilient bonding material 34 covers the bottom and top faces 24 and 25 of the body 20 and quantities of the bonding material 34 are interposed between and coat the opposed surfaces of the layers 30-33 within the laminate to bond the layers 30-33 together and to help provide the tapered cross section above discussed.

As seen in Figures 3 and 6, the layers 31-33 are of varying width. The bottom woven layer 30 is of substantial width, as measured between its convex and concave perimeter edges, and defines the shape, in plan, of the implant 10. The first intermediate felt layer 31 is of less width than bottom layer 30 and the second intermediate layer 32 is of lesser width than the first intermediate layer 31. Whereas the ends of the bottom woven layer 30 are semicircular, the ends of the intermediate felt layers 31 and 32 are generally much narrower and, in the embodiment shown, are pointed. The top woven layer 33 is generally similar in shape and size to the bottom layer 30 but may be slightly narrower in width.

As seen in Figure 6 (and in broken line in Figure 3), the layers 30-32 stacked one atop the other with the central portions of their convex perimeter edges vertically stacked and their ends and concave perimeter edges stepped progressively inboard. Due at least in part to its slope, the top cloth layer 33 preferably has its ends and concave perimeter edge slightly stepped inward from the corresponding edges of the bottom cloth layer 30, again as indicated in Figures 3 and 6.

This varying width of the layers and stepping of the ends and concave perimeter edges of the layers, along with the initial flowability of the resilient bonding material 34, determines the wedge shaped cross section of the implant 10.

A porous tube 40 (Figure 9), preferably of knitted fiber, may be of any desired hollow cross section, for example circular cross section. However, in the preferred embodiment shown, the tube 40 is of generally rectangular cross section, having four evenly circumferentially spaced crimped corners 41 integrally connecting the edges of four side walls 42. The tube 40 is however soft and pliable, and thus is readily deformable in shape. The porous material of the tube permits fibrous tissue grown by the patient to enter the adjacent open mesh of the side wall 42 and crimp corners 41 for interlocking the tube with the adjacent tissue of the patient in a manner more fully discussed hereafter.

Resilient bonding material 43 fixes one side wall 42' (Figures 2, 8 and 9) of the tube 40 to the relatively thick central portion of the convex perimeter edge 23 of the body 20. The tube 40 follows the convex perimeter edge 23 through about 180 to 200° of arc and is located symmetrically with respect thereto. The ends of the tube 40 are preferably trimmed at an angle, as indicated at 44 (Figures 1 and 8), so that the angle cut open ends 44 of the tube 40 lie substantially tangentially with respect to the curved, convex perimeter edge 23 of the body as the latter approaches the ends 21 of the body. In this way, the ends of the tube 40 blend smoothly into the shape of the body near the ends 21 thereof.

Preferably a high tensile strength tape 50 (Figures 1, 2 and 10) of woven fibers extends loosely through the tube 40 and has end portions extending considerably beyond the tube 40 and body 20 for purposes appearing hereafter.

While other materials may be employed, in the preferred embodiment shown, the following materials were found satisfactory.

Thus, the woven bottom and top cloth layers 30 and 33 were cut from commercially obtained sheets of woven polyester (e.g. Dacron TM) cloth. The wov-

en Dacron cloth is relatively thin, having a thickness approximately comparable to writing paper. The woven polyester fabric used in one unit made according to the invention was of a type already made for implantation in the cardiac field, e.g. for peri-cardium patches.

Also, the felt layers 31 and 32 were of felt-like material of matted polyester (e.g. Dacron TM or Teflon TM) material which is very soft and fluffy and whose surface has a fuzzy, fleece-like texture. The felt layers 31 and 32 are several times thicker than the woven fabric layers 30 and 33. In one unit constructed according to the invention, the felted layers, prior to coating, were of thickness approximately equal to or somewhat exceeding 0.16cm (1/16")

The above-mentioned woven and felted fabrics (at 30-33) are for example available from Meadox, located at Oakland, New Jersey, under the respective model nos. 019254 and 019304, 019306, 019314, 019316, 019324, and 019326.

Also, the tube 40 was knitted in a continuous length tubular configuration from polyester (e.g. Dacron TM) fiber of approximately one-quarter inch diameter. A suitable tube is available from Meadox located at Oakland, New Jersey under model no. 130-10.

Also, the tape 50 was of high tensile strength, woven polyester (e.g. Dacron TM) fiber. In the embodiment shown, the tape was about 0.3cm (one-eighth) inch wide and had a tensile load rating of about 70 kg (150 pounds). Suitable tape can be obtained from Meadox located at Oakland, New Jersey under model no. 130-20.

Also, the resilient bonding material employed was a polyurethane liquid used as a coating to bond to the above-discussed components (as detailed further hereafter), the coated members then being subjected to a curing step to remove the curing agent (dimethuracedimide) by subjecting the coated member to a special environment of controlled temperature and humidity in a conventional manner. Polyurethane bonding material marketed under the trademark Surethane, available from Cardiac Control Systems located at Palm Coast, Florida has been found suitable.

The cured polyurethane forms a smooth layer which tends to reject patient fiber ingrowth and tends to be, when coated with body liquids present in joints, slippery and of low friction, to simulate the similar characteristics of the natural meniscus cartilage.

Although dimensions may be varied at will to suit the needs of a particular patient cartilage to be replaced, in one particular medial meniscus cartilage constructed according to the invention, the length of the body 20 (measured horizontally in Figure 1) was about 4.4 cm (one and three-quarter inches), the maximum width thereof (measured along the vertical cutting line II-II in Figure 1) was about 1.3cm (one-half inch) and the shape was generally that shown in Figure 1, the thickness of the body 20 at its convex perimeter edge 23 maximum thickness being 0.5cm (3/16").

A favored method of manufacturing an implant 10 according to Figure 1 is as follows.

The flat, generally C-shaped layers 30-33 of woven fabric and matted material are cut to desired size and shape (depending on the size range and configuration of the type of natural cartilage to be replaced).

In making one unit, the woven bottom layer 30 was coated at least once (preferably twice) with the resilient bonding material 34, being cured after each coating. Unless otherwise stated hereafter, the coated layer (and the partial laminate formed as hereafter described) is laid flat during curing since it tends after curing to return resiliently to the shape (bent or flat) in which is maintained during curing. Curing was carried out by a conventional polyurethane curing method, in a conventional polyurethane curing chamber in which temperature and humidity are conventionally controlled.

Thereafter the top face of the bottom layer 30 was coated once again with the resilient bonding material and the first felt layer 31 was placed thereon in the manner generally indicated in dotted lines in the bottom portion of Figure 3, namely with the central convex edges of the layers vertically aligned. The resulting initial laminant 30, 31 was then cured.

Thereafter a coating of the resilient bonding material was applied atop the felted layer 31 and the coated surface of the underlying layer 30. The felted intermediate layer 32 was then placed upon the coated layer 31. The resulting partial laminant 30-32 was again subjected to curing of the resilient bonding material.

Thereafter, a coating of resilient bonding material was applied to both sides of the top woven fabric layer 33 and the top woven layer 33 was held in a three dimensional semi-circle shape, much like the shape of a segment of a rounded bowl, namely with the concave perimeter edge 60 substantially in one plane and the central portion 61 of the convex perimeter edge 62 spaced above the plane of the edge 60 by about the desired thickness of the central portion 26 of the convex perimeter edge 23 of the body 20 to be formed. This was done by pulling the ends of the coated top layer 33 from their normal planar position indicated at 63' in dotted lines in Figure 7, to a more closely laterally spaced position indicated in solid lines at 63 in Figure 7 and fixing, by means of pins 64 or the like, such ends 63 to a rigid substrate, such as a styrofoam plank and the result was subjected to curing. After curing the layer 33 tends to hold its thus distorted shape even when the pins 64 are removed and the layer 33 is removed from its substrate 65.

Preferably the layer 33 was given a second coating of resilient bonding material and again cured. Dur-

ing this second cure, the now double coated layer 33 may be once again temporarily secured by the pins 64 to the substrate 65 in its solid line position shown in Figure 7 so that it more rigidly is fixed in its distorted bowl segment shaped configuration.

Thereafter, a further coating of resilient bonding material 34 was placed atop the upper felted layer 32 and covered the exposed edges of the coated layers 31 and 30. The distorted, three dimensional bowl segment shaped layer 33 was then placed upon the coated underlying layers 30-32, and subjected to another curing step. This produced the generally wedge cross section laminated body 20 of Figure 6.

The coating penetrates only partway through the thickness of the felt layer so that a central thickness of the felt layer remains fluffy and pliable and substantially free of the resilient bonding material in the finished implant, such that the finished implant is pliable.

Thereafter, a further layer of resilient bonding material was applied to the convex perimeter edge 23 of the body 20 and the long side 42' of the end trimmed (at 44) tube 40 was placed thereagainst. The resulting structure was subjected to curing to firmly bond the tube 40 to the body 20 in the manner illustrated in Figures 1 and 2. It will be understood that the resilient bonding material 34 interpenetrates the openings in the knit side wall 42' of the tube 40, so that upon curing of the resilient bonding material to the usual resilient rubbery mass, the filaments of bonding material interpenetrating the openings of the knitted tube wall 42' firmly interlock together the tube 40 and body 20.

Optionally, before the tube 40 is subjected to contact with the resilient bonding material on the body 20, the tape 50 may be inserted through the trimmed tube 40 to extend beyond the ends thereof in the manner shown in Figure 1. Upon completion of the above described bonding of the tube 40 to the body 20 and curing of the intervening resilient bonding material 34, the tape 50 is thus caused to stay in place along the convex perimeter edge 23. As a practical matter, the resilient bonding material 34, prior to curing, may extend far enough through the opposed tube wall 42' to contact parts of the tape 50 and thereby endwise fix the tape 50 to the body 20. However, such endwise fixing is not essential.and it suffices that the tube 40 alone be bonded to the body 20, with the tape 50 free to run longitudinally in the tube 40.

OPERATION

As seen in Figure 11, the implant 10 here shown is insertable in place of the natural cartilage (here the medial meniscus cartilage) of the patient, to seat upon the top of the tibia 11 and assist in supporting the overlying condyle 13 of the femur. In time, natural fibrous tissue growth will enter the openings in the knitted fabric of the tube 40, such as the top and bottom surface thereof and particularly the lateral outboard facing surface 42" thereof, to firmly hold the implant 10 in place in the joint, while yet permitting a natural degree of sliding movement of the implant 10 with respect to the tibia 11 and condyle 13 during normal flexing of the joint.

Optionally, to help anchor the implant 10 in place during healing and fibrous tissue ingrowth, the surgeon may elect to utilize the exposed ends of the tape 50. This can be done, as shown in Figure 11, by boring angled holes 70 downward through the top of the tibia 11, to emerge at the sides thereof. The exposed ends of the tape 50 can then be extended down through such holes 70 and be secured, as by conventional surgical staples 71, to the side of the tibia 11, thereby limiting relative movement between the implant 10 and the opposed tibia 11 and condyle 13. If the surgeon decides he does not need to use the exposed ends of the tape 50 for anchoring purposes, he can simply trim same off where they emerge from the ends of the tube 40.

In use, the liquid normally present in the joint of the patient will coat the polyurethane coated and sealed bottom and top faces 24 and 25 of the implant 10 just as it would the corresponding bottom and top faces of a natural medial meniscus cartilage similarly located. The implant 10 will thus interact with the relatively moving tibia 11 and condyle 13 during patient movement of the joint, such as would a natural medial meniscus cartilage.

It will be understood that while the invention has been above disclosed, for illustrative purposes and by way of convenient example, in connection with a replacement for a medial meniscus cartilage in a patient, it is contemplated that the invention will also be applicable to other, more or less similar, cartilage replacement situations.

Claims

1. A soft tissue implant (10) in the form of meniscus cartilage replacement for a patient; comprising:

   a bottom layer (30);

   at least one felt intermediate layer (31) lying atop the bottom layer;

   a top layer (33) lying atop the or each felt layer;

   at least one coating (34) of a resilient bonding material coating the layers, the bonding material being interposed between the layers and fixing them together to form a laminated body (20) the layers being generally C-shaped in plan, so as to have a concave perimeter edge (22) and an oppositely facing convex perimeter edge (23) spaced across the width of the generally C-shaped body, the convex perimeter edge defining the

ends (21) of the generally C-shaped body, the or each felt intermediate layer having a width less than that of the top and bottom layers, and having its concave perimeter edge and ends inboard of the corresponding concave perimeter edge and ends of the top and bottom layers, making the body taper in central cross-section from a thin concave perimeter edge to a much thicker convex perimeter edge, the convex perimeter edge tapering to reduce its thickness toward the ends of the body, the body thus having a generally wedge shaped central cross-section, the top layer thereby being distorted to a three dimensional, generally bowl, shape.

2. A soft tissue implant (10) according to claim 1 in which the three dimensional shape of the top layer (33) is comparable to that achieved by slightly moving toward each other the remote ends of a flexible flat C-shaped sheet.

3. A soft tissue implant (10) according to claim 1 or 2 in which the layers are of polyester fiber and the bonding material is polyurethane.

4. A soft tissue implant (10) according to any preceding claim in which the thin concave perimeter edge (22) is a feather edge.

5. A soft tissue implant (10) according to any preceding claim in which the or each felt layer (31) is of a fluffy, random filament, pliable material, the coating (34) penetrating only partway through the thickness of the felt layer so that a central thickness of the felt layer remains fluffy and pliable and substantially free of the bonding material in the finished implant, so that the finished implant is pliable.

6. A soft tissue implant (10) in the form of meniscus cartilage replacement for a patient, comprising:

a bottom layer (30);

at least one felt intermediate layer (31) lying atop the bottom layer;

a top layer (33) lying atop the or each felt layer;

at least one coating (34) of a resilient bonding material coating the layers, the bonding material being interposed between the layers and fixing them together to form a laminated body (20), the body having spaced apart ends (21) and a perimeter edge (23) extending between the ends, the body being wedge shaped in central cross-section with greatest thickness in the central portion of the perimeter edge and extending towards the end of the body; an elongate tube of porous material extending along the perimeter edge and having one side (42') abutting the perimeter edge and a layer (43) of resilient bonding material interposed therebetween and bonding the side of the tube to the perimeter edge from the greatest thickness central portion substantially to the ends, the last-mentioned resilient bonding material bonding to the wedge shaped body (20) and being interlocked in the material of the tube, the tube having a hollow central portion extending from end to end thereof, at least the side of the tube opposite the said one side (42') being free of the resilient bonding material so that the material thereof is free to become interlocked with eventual adjacent tissue growth in a patient.

7. A soft tissue implant (10) according to claim 6 including a high tensile strength tape (50) extending through the tube (40) and well beyond the ends (44) thereof and forming a pair of temporary ties, the tape having ends capable of being led through holes in adjacent bones of a patient and anchored tightly thereto for holding the body (20) and attached tape in place while awaiting ingrowth of tissue to interlock with the opposite side of the tube.

8. A soft tissue implant (10) according to claim 6 or 7 in which the body (20) is substantially C-shaped in plan so that the perimeter edge (23) and tube (40) bonded thereto are convexly curved.

9. A soft tissue implant (10) according to claim 8 in which the ends (44) of the tube (40) are trimmed at an angle so as to extend substantially tangentially to the convex perimeter edge (23) of the body (20) near the ends thereof.

10. A soft tissue implant (10) according to claim 8 or 9 in which the generally C-shaped body (20) has also a concave perimeter edge (22) connecting the body ends (21) and which defines the thin end of the wedge shaped cross-section, the concave perimeter being of negligible thickness compared to the perimeter edge (23) opposite thereto bonded to the tube (40).

11. A soft tissue implant (10) according to any of claims 6 to 10 in which the tube (40) is of knitted polyester and the tape (50) is of polyester.

12. A method of making a meniscus cartilage replacement implantable in a patient, comprising:

(a) providing flat generally C-shaped layers of thin and of felted material and sizing the or each felted material layer smaller in plan than the thin layers;

(b) coating a generally C-shaped thin layer with a resilient bonding material and then curing the latter to form a bottom layer;

(c) superposing one at a time on the bottom layer at least one felted layer, the superposing including the steps of coating at least one of the opposed faces of the bottom layer and a felted material layer with a resilient bonding material, placing the latter layers together with their convex edges superposed so the concave edge of the felted material layer is spaced inboard of the concave edge of the bottom layer, the last-mentioned felted material layer constituting a first intermediate layer, and then curing the resulting laminate;
(d) coating a second flat, generally C-shaped thin layer with resilient bonding material, fixedly securing the ends thereof on a substrate at a reduced distance from each other so that the second layer is distorted into a three dimensional, bowl segment shape, and curing the coated second layer in the three dimensional, bowl segment shape to form a top layer;
(e) coating at least one of the top face of the intermediate laminate and bottom face of the three dimensional, bowl segment shaped top layer with a resilient bonding material, placing the latter on the former with their convex edges superposed so the concave edge of the top layer is substantially adjacent to the concave edge of the bottom layer, and then curing the resulting multi-layer laminate, the convex edge of the laminate thus being several times thicker than the concave edge thereof; and
(f) coating at least one of the opposed faces of the convex edge of the multilayer laminate and a tube of porous fabric with a resilient bonding material, pressing the opposed faces together and then curing the resultant meniscus cartilage replacement.

13. A method according to claim 12 including trimming the ends of the tube at an angle so as to be substantially tangential to the ends of the multilayer laminate.

14. A method according to claim 12 or 13 including, prior to step (f), the insertion of a high tensile strength tape through the tube such that the ends of the tape protrude from the ends of the tube.

15. A method according to claim 14, the ends of the tape having means capable of being led through holes in adjacent bones of a patient and anchored tightly thereto for holding the body and attached tape in place while awaiting growth of tissue to interlock with the opposite side of the tube.

16. A method according to any of claims 12 to 15 including the further step of repeating step (c) with at least a second felted material layer placed on the first mentioned felted material layer to form at least a three layer intermediate laminate.

17. A method according to any of claims 12 to 16 in which the layers are of polyester fiber and the bonding material is polyurethane.

18. A soft tissue implant (10) in the form of meniscus cartilage replacement for a patient, comprising:
a bottom layer (30);
at least one felt intermediate layer (31) lying atop the bottom layer;
a top layer (33) lying atop the or each felt layer;
at least one coating (34) of a resilient bonding material coating the layers, the bonding material being interposed between the layers and fixing them together to form a laminated body (20), the body having spaced apart ends (21) and a perimeter edge (23) extending between the ends, the body being wedge shaped in central cross-section with greatest thickness in the central portion of the perimeter edge (23) and extending towards the end of the body.

19. A soft tissue implant according to any of claims 1 to 11 and 18 in which the bottom layer (30) and the top layer (33) are formed of a woven cloth material.

20. A method of making a meniscus cartilage replacement according to any of claims 12 to 17 in which the bottom layer (30) and the top layer (33) are formed of a woven cloth material.

Patentansprüche

1. Implantat (10) aus Weichgewebe, in Form eines Meniskusknorpelersatzes für einen Patienten, enthaltend: eine Basisschicht (30); mindestens eine auf der Basisschicht aufliegende Filzzwischenschicht (31); eine auf der oder jeder Filzschicht aufliegende Deckschicht (33); mindestens ein auf die Schichten aufgebrachter Belag (34) eines elastischen Bindematerials, der zwischen den Schichten angeordnet diese zur Bildung eines mehrlagigen Körpers (20) miteinander verbindet, wobei die Schichten im Grundriss im wesentlichen C-förmig sind, so dass sie über die Breite des C-förmigen Körpers distanziert eine konkave periphere Kante (22) und eine dieser gegenüberliegende konvexe periphere Kante (23) aufweisen, und die konvexe periphere Kante die Enden (21) des im wesentlichen C-förmigen

Körpers bestimmt, und wobei ferner die Breite der oder jeder Filzzwischenschicht geringer ist als diejenige der Basis- und der Deckschicht und ihre konkave periphere Kante und Enden einwärts der entsprechenden konkaven peripheren Kante und Enden der Basis- und Deckschicht verlaufen, sodass sich der Körper im Querschnitt von einer dünnen, konkaven, peripheren Kante zu einer wesentlich dickeren, konvexen, peripheren Kante erweitert, wobei sich die konvexe periphere Kante gegen die Enden des Körpers hin zur Verringerung ihrer Dicke verjüngt, sodass der Körper einen im wesentlichen keilförmigen mittleren Querschnitt aufweist und sich die Deckschicht hierbei zu einer dreidimensionalen, generell schalenförmigen Form deformiert.

2. Weichgewebe-Implantat (10) nach Anspruch 1, dadurch gekennzeichnet, dass die dreidimensionale Form der Deckschicht (33) vergleichbar ist der Form, welche beim etwas aufeinander zu bewegen der entfernten Enden eines flexiblen, flachen, C-förmigen Blatts entsteht.

3. Weichgewebe-Implantat (10) nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Schichten aus Polyesterfasern bestehen und das Bindematerial Polyurethan ist.

4. Weichgewebe-Implantat (10) nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die dünne, konkave periphere Kante (22) eine gefederte Kante ist.

5. Weichgewebe-Implantat (10) nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die oder jede Filzschicht (31) aus einem flaumigen, biegbaren Material mit ungeordneten Filamenten besteht und der Belag (34) nur teilweise in die Dicke der Filzschicht eindringt, sodass im fertigen Implantat ein zentraler Bereich der Dicke der Filzschicht flaumig, biegbar und im wesentlichen frei von Bindematerial bleibt und dadurch das fertige Implantat biegbar bleibt.

6. Implantat (10) aus Weichgewebe, in Form eines Meniskusknorpelersatzes für einen Patienten, enthaltend: eine Basisschicht (30); mindestens eine auf der Basisschicht aufliegende Filzzwischenschicht (31); eine auf der oder jeder Filzschicht aufliegende Deckschicht (33); mindestens ein auf die Schichten aufgebrachter Belag (34) eines elastischen Bindematerials, der zwischen den Schichten angeordnet diese zur Bildung eines mehrlagigen Körpers (20) miteinander verbindet, wobei der Körper voneinander distanzierte Enden und eine zwischen diesen verlaufende periphere Kante (23) aufweist, der Körper ferner einen keilförmigen zentralen Querschnitt besitzt, mit seiner grössten Dicke im zentralen Bereich der peripheren Kante (23) und gegen die Enden des Körpers hin verlaufend; ein längliches Rohr aus porösem Material, das sich entlang der peripheren Kante erstreckt und mit einer Seite (42') an der peripheren Kante anliegt, und eine dazwischen angeordnete Schicht (43) aus elastischem Bindematerial, welche, vom zentralen Bereich mit grösster Dicke im wesentlichen bis zu den Enden, die Seite des Rohrs mit der peripheren Kante verbindet, wobei das letztgenannte elastische Bindematerial am keilförmigen Körper (20) haftet und im Material des Rohrs verkettet ist, wobei das Rohr eine hohlen zentralen Abschnitt aufweist, der sich von Ende zu Ende erstreckt, und mindestens die der genannten Seite (42') gegenüberliegende Seite des Rohrs frei von elastischem Bindematerial ist, sodass dort das Rohrmaterial mit eventuell zuwachsemdem, benachbartem Gewebe eines Patienten verwachsen kann.

7. Weichgewebe-Implantat (10) nach Anspruch 6, dadurch gekennzeichnet, dass durch das Rohr (40) und weit über dessen Enden (44) hinaus ein Band (50) hoher Zugfestigkeit geführt ist, welches ein Paar temporärer Befestigungen bildet, wobei die Bandenden durch Oeffnungen in benachbarten Knochen des Patienten führbar und mit diesen verankerbar sind, um den Körper (20) und das befestigte Band zu fixieren bis der Gewebezuwachs mit den gegenüberliegenden Seiten des Rohrs verwächst.

8. Weichgewebe-Implantat (10) nach Anspruch 6 oder 7, dadurch gekennzeichnet, dass der Körper (20) einen im wesentlichen C-förmigen Grundriss besitzt, sodass die periphere Kante (23) und das damit verbundene Rohr (40) konvex gekrümmt sind.

9. Weichgewebe-Implantat (10) nach Anspruch 8, dadurch gekennzeichnet, dass die Enden (44) des Rohrs (40) winklig geformt sind, sodass sie im wesentlichen tangential zur konvexen peripheren Kante (23) des Körpers (20) nahe der Enden desselben verlaufen.

10. Weichgewebe-Implantat (10) nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass der im wesentlichen C-förmige Körper (20) auch eine seine Enden (21) verbindende konkave periphere Kante (22) aufweist, welche das dünne Ende des keilförmigen Querschnitts bildet, und dass die Dicke des konkaven Umfangs vernachlässigbar ist im Vergleich zu derjenigen der ihr gegenüberlie-

genden, mit dem Rohr (40) verbundenen, peripheren Kante (23).

11. Weichgewebe-Implantat (10) nach einem der Ansprüche 6 bis 10, dadurch gekennzeichnet, dass das Rohr (40) aus Polyestergewirk und das Band (50) aus Polyester besteht.

12. Verfahren zur Herstellung eines einem Patienten implantierbaren Meniskusknorpelersatzes, bei welchem:
(a) flache, im wesentlichen C-förmige Schichten aus dünnen und aus Filzmaterial so dimensioniert werden, dass die Filzschichten einen kleineren Grundriss aufweisen als die dünnen Schichten;
(b) eine im wesentlichen C-förmige, dünne Schicht mit einem elastischen Bindemittel beschichtet und letzteres gehärtet wird um eine Basisschicht zu bilden;
(c) auf diese Basisschicht nacheinander mindestens eine Filzschicht aufgelegt wird, wobei dieses Aufeinanderlegen die Verfahrensschritte umfasst, dass mindestens eine der einander gegenüberliegenden Flächen der Basisschicht und einer Schicht aus Filzmaterial mit einem elastischen Bindenmaterial beschichtet werden, die letztgenannten Schichten mit ihren konvexen Kanten übereinander derart zusammengefügt werden, dass die konkave Kante der Filzmaterialschicht mit Abstand einwärts der konkaven Schicht der Basisschicht verläuft, wobei die zuletzt genannte Filzmaterialschicht eine erste Zwischenschicht bildet, und dass dann das resultierende Laminat ausgehärtet wird;
(d) eine zweite, flache, im wesentlichen C-förmige, dünne Schicht mit elastischem Bindematerial beschichtet wird, die Enden dieser Schicht mit vermindertem Abstand fest derart auf einem Substrat befestigt werden, dass die zweite Schicht zu einer dreidimensionalen, schalenförmigen Segmentform verformt wird, und die zweite Schicht in dieser dreidimensionalen, schalenförmigen Segmentform gehärtet wird um eine Deckschicht zu bilden;
(e) mindestens eine der oberen Fläche des Zwischenlaminats und der Bodenfläche der dreidimensionalen, schalensegementförmigen Deckschicht mit einem elastischen Bindematerial beschichtet wird, letztere so auf erstere gelegt wird, dass ihre konvexen Kanten aufeinanderliegen, sodass die konkave Kante der Deckschicht im wesentlichen benachbart der konkaven Kante der Basisschicht verläuft, und hierauf das resultierende, mehrlagige Laminat gehärtet wird, wobei die konvexe Kante des Laminats um ein mehrfaches dicker ist als seine konkave Kante; und
(f) mindestens eine der einander gegenüberliegenden Flächen der konvexen Kante der mehrlagigen Laminats und ein. Rohr aus porösem Gewebe mit einem elastischen Bindematerial beschichtet werden, die einander gegenüberliegenden Seiten gegeneinander gepresst werden und danach der resultierende Meniskusknorpelersatz gehärtet wird.

13. Verfahren nach Anspruch 12, dadurch gekennzeichnet, dass die Enden des Rohrs winklig getrimmt sind, sodass sie im wesentlichen tangential zu den Enden des mehrlagigen Laminats verlaufen.

14. Verfahren nach Anspruch 12 oder 13, dadurch gekennzeichnet, dass vor dem Schritt (f) ein Band hoher Zugfestigkeit so durch das Rohr geführt wird, dass die Bandenden über die Enden des Rohrs vorragen.

15. Verfahren nach Anspruch 14, dadurch gekennzeichnet, dass die Bandenden Mittel zu ihrem Durchführen durch Oeffnungen in benachbarten Knochen eines Patienten und zur festen Verankerung in diesen aufweisen, um den Körper und das befestigte Band zu fixieren bis der Gewebezuwachs mit den gegenüberliegenden Seiten des Rohrs verwächst.

16. Verfahren nach einem der Ansprüche 12 bis 15, dadurch gekennzeichnet, dass Schritt (c) mit mindestens einer zweiten, auf die ersterwähnte Filzmaterialschicht aufgelegten Filzmaterialschicht wiederholt wird, um ein mindestens dreilagiges Zwischenlaminat zu bilden.

17. Verfahren nach einem der Ansprüche 12 bis 16, dadurch gekennzeichnet, dass die Schichten aus Polyesterfasern bestehen und das Bindematerial Polyurethan ist.

18. Implantat (10) aus Weichgewebe, in Form eines Meniskusknorpelersatzes für einen Patienten, enthaltend: eine Basisschicht (30); mindestens eine auf der Basisschicht aufliegende Filzzwischenschicht (31); eine auf der oder jeder Filzschicht aufliegende Deckschicht (33); mindestens ein auf die Schichten aufgebrachter Belag (34) eines elastischen Bindematerials, der, zwischen den Schichten angeordnet, diese zur Bildung eines mehrlagigen Körpers (20) miteinander verbindet, wobei der Körper distanzierte Enden (21) und dazwischen eine periphere Kante (23) aufweist, wobei der Körper im zentralen Querschnitt keilförmig ist, mit der grössten Dicke im zentralen Bereich der peripheren Kante (23)

und gegen die Enden des Körpers hin verlaufend.

19. Weichgewebe-Implantat nach einem der Ansprüche 1 bis 11 und 18, dadurch gekennzeichnet, dass die Basisschicht (30) und die Deckschicht (33) aus gewobenem textilem Material gebildet sind.

20. Verfahren zur Herstellung eines Meniskusknorpelersatzes nach einem der Ansprüche 12 und 17, dadurch gekennzeichnet, dass die Basisschicht (30) und die Deckschicht (33) aus gewobenem textilem Material gebildet sind.

Revendications

1. Un implant (10) de tissu mou en forme d'un cartilage de ménisque de remplacement pour un patient, comprenant: une couche de fond (30); au moins une couche intermédiaire (31) en feutre disposée sur la couche de fond; une couche de dessus (33) disposée sur le ou chaque couche en feutre; au moins un enduit (34) d'une matière adhésive élastique enduisant les couches, la matière adhésive étant interposée entre les couches et les fixant entre elles pour former un corps (20) laminé, les couches étant généralement de forme en C en plan, de manière à présenter un bord périmétrique concave (22) et, sur le côté opposé, un bord périmétrique convexe (23) espacé sur la largeur du corps de forme générale en C, le bord périmétrique convexe formant les extrémités (21) du corps de forme générale en C, la couche ou chaque couche intermédiaire en feutre ayant une largeur inférieure à celle des couches de fond et de dessus, et ayant son bord périmétrique concave et ses extrémités à l'intérieur du bord périmétrique concave et des extrémités des couches de fond et de dessus correspondantes, faisant ainsi que la section centrale du corps aille en augmentant d'un bord périmétrique concave mince vers un bord périmétrique convexe sensiblement plus épais, le bord périmétrique convexe se rajeunissant de façon à réduire son épaisseur vers les extrémités du corps, ce dernier présentant ainsi une section centrale ayant la forme générale d'un coin, la couche supérieure étant déformée en une forme tridimensionnelle ayant la forme générale d'un bol.

2. Un implant de tissu mou (10) selon la revendication 1, caractérisé en ce que la forme tridimensionnelle de la couche de dessus (33) est comparable à celle obtenue en déplaçant légèrement contre elles les extrémités distantes d'une feuille plate et flexible en forme de C.

3. Un implant de tissu mou (10) selon la revendication 1 ou 2, caractérisé en ce que les couches sont en fibre de polyester et la matière adhésive est du polyuréthane.

4. Un implant de tissu mou (10) selon l'une des revendications précédentes, caractérisé en ce que le bord périmétrique mince concave (22) est un bord en biseau.

5. Un implant de tissu mou (10) selon l'une des revendications précédentes, caractérisé en ce que la ou chaque couche en feutre (31) est en une matière pliable, pelucheuse à filaments désordonnés, l'enduit (34) ne pénétrant que partiellement l'épaisseur de la couche en feutre, pour que, dans l'implant terminé, une épaisseur centrale de la couche en feutre reste pelucheuse et pliable et sensiblement libre de matière adhésive de sorte que l'implant terminé est pliable.

6. Un implant (10) de tissu mou en forme d'un cartilage de ménisque de remplacement pour un patient, comprenant: une couche de fond (30); au moins une couche intermédiaire (31) en feutre disposée sur la couche de fond; une couche de dessus (33) disposée sur le ou chaque couche en feutre; au moins un enduit (34) d'une matière adhésive élastique enduisant les couches, la matière adhésive étant interposée entre les couches et les fixant entre elles pour former un corps (20) laminé, le corps ayant de extrémités (21) espacées et un bord périmétrique (23) qui s'étend entre les extrémités, le corps présentant une section centrale ayant la forme d'un coin avec son épaisseur maximale dans la partie centrale du bord périmétrique (23) et s'étendant vers l'extrémité du corps; un tube allongé en matière poreuse s'étendant le long du bord périmétrique et ayant un côté (42') touchant le bord périmétrique avec, interposée entre les deux, une couche (43) de matière adhésive élastique qui colle le côté du tube au bord périmétrique depuis la partie centrale à épaisseur maximale sensiblement jusqu'aux extrémités, ladite matière adhésive élastique collant au corps (20) en forme de coin et étant entrelacée avec la matière du tube, ce dernier présentant une partie centrale creuse s'étendant d'un bout à l'autre de ce tube, au moins le côté du tube qui est à l'opposé dudit côté (42') étant libre de matière adhésive élastique de sorte que sa matière puisse s'entrelacer avec du tissu du patient croissant au voisinage.

7. Un implant de tissu mou (10) selon la revendication 6, caractérisé en ce qu'il comporte un ruban (50) à haute résistance à la traction, qui s'étend à travers le tube (40) et bien au-delà des extré-

mités (44) de celui-ci et qui forme une paire d'attaches temporaires, le ruban ayant des extrémités susceptibles d'être c'onduites à travers des ouvertures d'os adjacents d'un patient et d'être ancrées fermement à ceux-ci pour maintenir en place le corps (20) et le ruban attaché en attendant la croissance de tissu venant s'entrelacer avec le côté opposé du tube.

8. Un implant de tissu mou (10) selon la revendication 6 ou 7, caractérisé en ce que le corps (20) est sensiblement de forme en C vu en plan de sorte que le bord périmétrique (23) et le tube (40) qui y est collé sont incurvés convexement.

9. Un implant de tissu mou (10) selon la revendication 8, caractérisé en ce que les extrémités (44) du tube (40) se terminent en angle de façon à s'étendre sensiblement tangentiellement au bord périmétrique convexe (23) du corps (20) à proximité des extrémités de celui-ci.

10. Un implant de tissu mou (10) selon la revendication 8 ou 9, caractérisé en ce que le corps (20) de forme générale en C présente également un bord périmétrique concave (22) reliant ses extrémités (21) et formant l'extrémité mince de la section en forme de coin, l'épaisseur du périmètre concave étant négligeable comparée au bord périmétrique opposé qui est collé au tube (40).

11. Un implant de tissu mou (10) selon l'une des revendications 6 à 10, caractérisé en ce que le tube (40) est en bonneterie en polyester et le ruban (50) est en polyester.

12. Un procédé de fabrication d'un cartilage de ménisque de remplacement implantable à un patient, consistant:

(a) à préparer des couches plates ayant la forme générale d'un C en matière mince et en matière de feutre, et à dimensionner la ou chaque couche en matière de feutre de façon à ce qu'elle ait, vue en plan, une dimension inférieure à celle des couches minces;

(b) à enduire une couche mince en forme générale d'un C d'une matière adhésive élastique et ensuite à durcir cette dernière pour former une couche de fond;

(c) à superposer une à une sur la couche de fond au moins une couche de feutre, la superposition comprenant les étapes consistant à enduire au moins l'une des surfaces se faisant face de la couche de fond et d'une couche en matière de feutre d'une matière adhésive élastique, à réunir ces couches avec leur bords convexes superposés, de sorte que le bord concave de la couche de feutre soit espacé vers l'intérieur du bord concave de la couche de fond, la couche de feutre mentionnée en dernier constituant une première couche intermédiaire, et à durcir le stratifié résultant;

(d) à enduire une seconde couche mince et plate, de forme générale en C, d'une matière adhésive élastique , à fixer fermement ses extrémités à une distance réduite à un substrat de sorte que la seconde couche soit déformée en une forme de segment de bol tridimensionnelle, et à durcir la seconde couche enduite dans la forme tridimensionnelle de segment de bol pour former une couche de dessus;

(e) à enduire d'une matière adhésive élastique au moins l'une des surfaces supérieures du stratifié intermédiaire et la surface inférieure de la couche de dessus tridimensionnelle en forme de segment de bol, à placer cette dernière sur la précédente avec leurs bords convexes superposés de sorte que le bord concave de la couche de dessus soit sensiblement voisin du bord concave de la couche de fond, et ensuite à durcir le stratifié à couches multiples résultant, le bord convexe du stratifié ayant, de la sorte, une épaisseur qui est plusieurs fois supérieure à son bord concave; et

(f) à enduire d'une matière adhésive élastique au moins l'une des faces opposées du bord convexe du stratifié à couches multiples et d'un tube en tissu poreux, à presser les faces opposées l'une contre l'autre et à durcir le cartilage de ménisque de remplacement résultant.

13. Procédé selon la revendication 12, caractérisé en ce que les extrémités du tube sont effilées à un angle de manière à ce qu'elles soient tangentielles aux extrémités du stratifié à couches multiples.

14. Procédé selon la revendication 12 ou 13, caractérisé en ce qu'il comporte, précédant l'étape (f), l'insertion d'un ruban à haute résistance à la traction à travers le tube de façon à ce que les extrémités du ruban dépassent des extrémités du tube.

15. Procédé selon la revendication 14, caractérisé en ce que les extrémités du ruban sont munies de moyens capables d'être conduits à travers des ouvertures dans des os voisins d'un patient et ancrés fixement à ces os pour tenir en place le corps et le ruban attaché en attendant la croissance de tissus s'entrelaçant avec le côté opposé du tube.

16. Procédé selon l'une des revendications 12 à 15, caractérisé en ce qu'il comporte l'étape additionnelle de répéter l'étape (c) avec au moins une seconde couche de matière en feutre placée sur la couche en matière de feutre mentionnée en premier, pour former un stratifié intermédiaire composé d'au moins trois couches.

17. Procédé selon l'une des revendications 12 à 16, caractérisé en ce que les couches sont en fibres de polyester et la matière adhésive élastique est du polyuréthane.

18. Un implant (10) de tissu mou en forme d'un cartilage de ménisque de remplacement pour un patient, comprenant: une couche de fond (30); au moins une couche intermédiaire (31) en feutre disposée sur la couche de fond; une couche de dessus (33) disposée sur la ou chaque couche en feutre; au moins un enduit (34) d'une matière adhésive élastique enduisant les couches, la matière adhésive étant interposée entre les couches et les fixant entre elles pour former un corps (20) stratifié, le corps ayant des extrémités espacées (21) et un bord périmétrique (23) s'étendant entre ces extrémités, le corps ayant une section centrale en forme de coin ayant son épaisseur maximale dans la partie centrale du bord (23) périmétrique et s'étendant vers l'extrémité du corps.

19. Un implant (10) de tissu mou selon l'une quelconque des revendications 1 à 11 et 18, caractérisé en ce que la couche de fond (30) et la couche de dessus (33) sont formées d'une matière textile tissée.

20. Un procédé de fabrication d'un cartilage de ménisque de remplacement selon l'une quelconque des revendications 12 à 17, caractérisé en ce que la couche de fond (30) et la couche de dessus (33) sont formées d'une matière textile tissée.

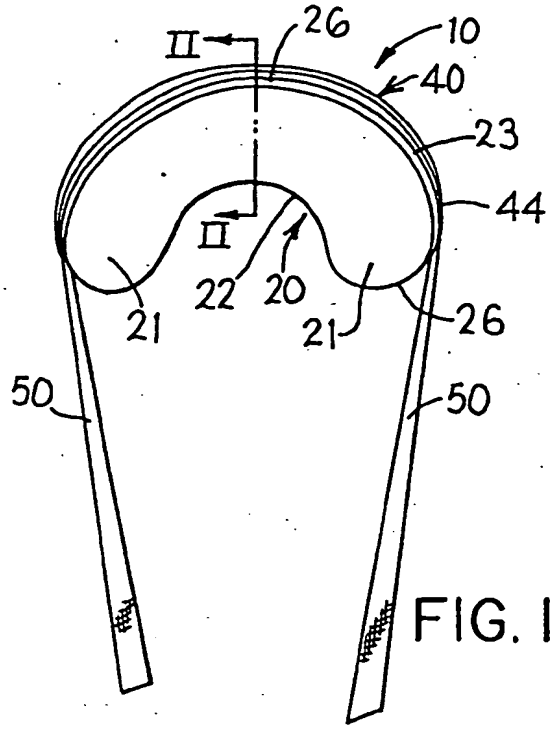

FIG. 1

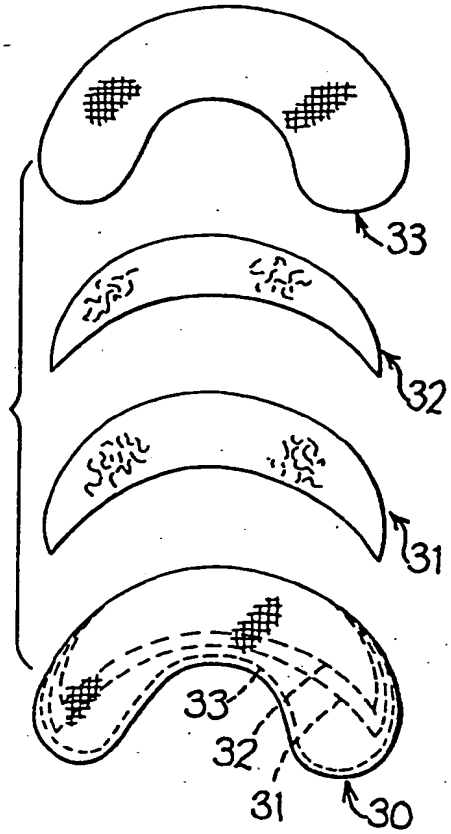

FIG. 3

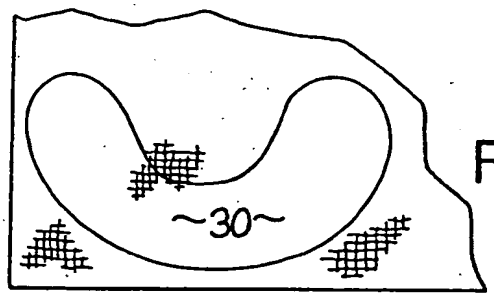

FIG. 4A

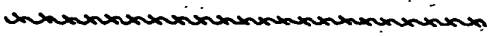

FIG. 4B

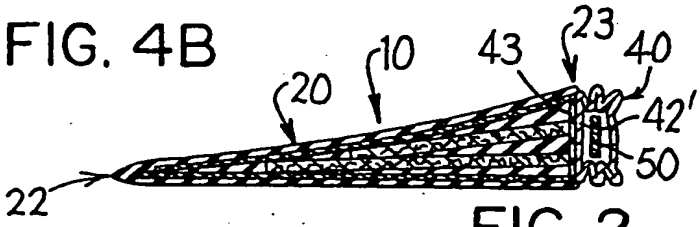

FIG. 2

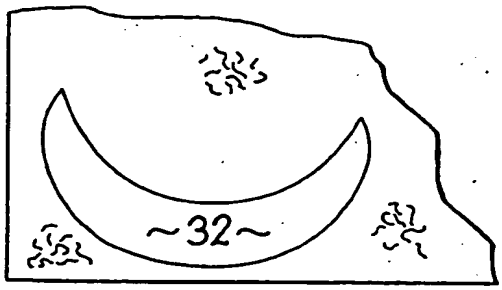

FIG. 5A

FIG. 5B

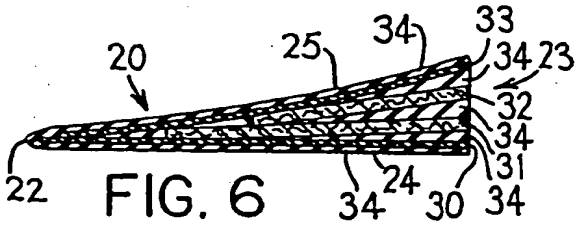

FIG. 6

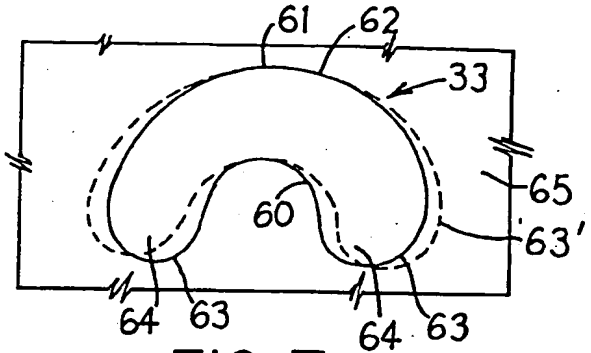

FIG. 7

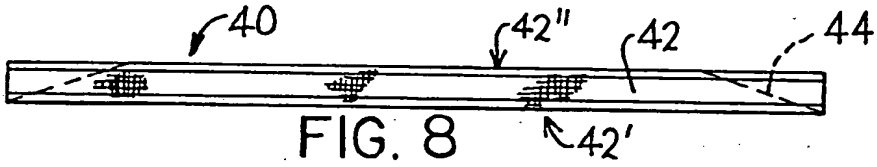

FIG. 8

FIG. 10

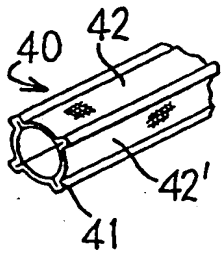

FIG. 9

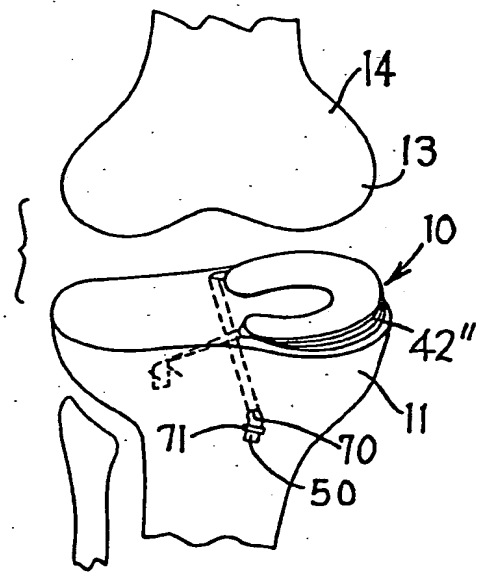

FIG. 11